REMARKS

A. Summary of the Invention and Claim Amendments.

After amendment, Claims 1-4, 8, 10, 12-16, 19, 21, 32 and 34-41 are pending. The claimed invention provides the art with the discovery that fatty acid esters, such as isopropyl myristate, can be used to rapidly kill ectoparasites such as lice without application of other pediculocidal agents.

Claims 1 and 12 are also amended to specify that isopropyl myristate is present in an amount effective to kill ectoparasites alone, in a concentration of up to 100%, consistent with the Specification at, for example, paragraphs [0011] and [0039]. Efficacy of at least about a 50% kill rate within an hour is also specified, consistent with the Specification at, for example, paragraphs [0036] (about 52% at half strength) and [0040] (about 82% at full strength).

Newly added Claims 34-38 are to killing ectoparasites as recited through exposure to the recited formulation for 10 minutes. They are supported in the Specification by, for example, paragraphs [0007], [0008], [0011], [0036] and [0039].

Newly added Claims 39-41 are to use of particular concentrations of isopropyl myristate. They are supported in the Specification by, for example, paragraphs [0011], [0020], [0036] and [0040].

No new matter being added to the Specification, entry of the proposed amendment is therefore requested. The Examiner's consideration of the claims as amended is appreciated.

B. Response to Rejection under Section 112, First Paragraph.

Claims 1-4, 8, 10, 12-15, 19, 21 and 32 are rejected for lack of enablement on the asserted basis that the invention is not enabled for "any carrier(s)." Applicants respectfully disagree.

As claimed, isopropyl myristate is provided as the sole killing agent in the compositions whose use against lice is claimed. The claim is supported by the Specification, which instructs that "*just fatty acid esters alone*, preferably isopropyl myristate, have the effect of killing ectoparasites" (paragraph [0011]). To that end, the Specification teaches application of isopropyl myristate at concentrations "effective" for killing lice (paragraph [0007]) of up to 100% (paragraph [020]); i.e., with no other killing agent and irrespective of carrier. Silicones such as cyclomethicone are disclosed as also having that ability, but their use is not required (see, paragraph [0011] and [0020]—use of isopropyl myristate alone).

Where isopropyl myristate is used as the killing agent, the Specification explicitly teaches that "[i]n those embodiments comprising only myristate, the myristate can be used at 100% or mixed with another desirable carrier *other than a siloxane*" (paragraph [0027], emphasis added). In such instances, the carrier is not serving as an active, and so any suitable carrier will do. Examples of suitable carriers are provided, and there can be no question that one of ordinary skill in the pharmaceutical arts will be more than familiar with others.

The Office Action offers no reason why the use of isopropyl myristate as the killing agent against lice in any suitable pharmaceutical carrier is not enabled by the Specification. Nor are Applicants aware of any reason why mixing isopropyl myristate in a suitable pharmaceutical carrier would be beyond the skills of any ordinary artisan.

As to the isopropyl myristate itself, no reason is offered in the Office Action (nor are Applicants aware of one) for why one of ordinary skill could not apply the teachings of the Specification to the use of isopropyl myristate as claimed. To the contrary, its use is demonstrated in the Specification both in pure form and at lower concentrations (see, e.g., paragraphs [0039], [0036], [0042] and [0043]), with killing times within those recited in the claims.

Applicants therefore submit that the claims are fully enabled by the Specification across their scope, and that one would reasonably expect the Specification to be accurate in its assessment that "*just fatty acid esters alone*, preferably isopropyl myristate, have the effect of killing ectoparasites" (paragraph [0011]), absent proof to the contrary. No such evidence being provided, no *prima facie* case for lack of enablement has been shown.

To expedite prosecution, however, the claims have now been amended to clarify a particularly vigorous range of efficacy for isopropyl myristate. This amendment is made without acquiescence in the basis of the rejection or waiver of Applicants right to pursue broader claims in the future, as supported by the Specification.

For all of the above reasons, reconsideration and withdrawal of the rejection under Section 112, first paragraph is respectfully requested.

C. Response to Rejection under Section 103, based on Pearlman.

Claims 1-4, 12-15, and 32 stand rejected under Section 103, based on Pearlman, US Patent No. 6,303,581. The rejection is referred to in the Action as being a continued one (page 3, second paragraph). However, in the prior Action, the Pearlman reference was asserted only in an anticipation rejection under Section 102(a) and/or (e). Applicants therefore assume that the anticipation rejection is now withdrawn in favor of the present rejection under Section 103, and respond herein accordingly.

Applicants respectfully submit that the present rejection misstates the teachings of the Pearlman reference. The Action states that "PEARLMAN shows human head lice, treated within 6 seconds to 2 hours, and combed out (summary, lines 40-67 and 2nd paragraph, column 3) after drying by evaporation and heating. The driable *pediculostatic* agent is applied at 0.1 to 100% (column 11, lines 22-23, 36-40) with a silicone (column 12, lines 34-38). No patentable weight is given to how the ectoparasites *are killed*—application of the same active, fatty esters, including IPM, would result in the same effects. This is the instant method step." (Action at page 3, first paragraph, emphasis added).

Applicants disagree. The above statement appears to equate teaching of a *pediculostatic* effect, clearly defined by Pearlman as meaning that lice are merely immobilized, with *killing* lice, as presently claimed. That reading of Pearlman is directly inconsistent with the reference's explicit teachings.

As defined by Pearlman, the term "pediculostatic" refers to the effect of an agent in triggering a so-called 'immersion reflex' in lice which immobilizes them, making it easier to remove them from the host (Col. 2, lines 42-53; Col. 4, lines 19-31; . The reference distinguishes such action from those considered effective in the prior art, which are characterized as being pediculocidal; i.e., killing agents (see, e.g., Col. 4, lines 35-39). Pediculostatic agents of the Pearlman compositions are characterized as being novel for their ability to "stun or immobilize" lice rather than killing them (Col. 4, lines 60-63).

Pearlman acknowledges that leaving his pediculostatic agents "usually at least about 2 to 8 hours, typically overnight" will eventually cause lice to be killed (Col. 3, lines 37-42). However, for the "6 seconds to 2 hours" period referred to in the Office Action, Pearlman clearly acknowledges that his pediculostatic agents do not kill lice, but only "induce the immersion reflex" that quickly to immobilize them (Col. 3, lines 19-31). Therefore, the Action's reading of this passage of Pearlman at Column 3 as suggesting lice are *killed*

within the 6 seconds to 2 hour time frame is directly at odds with the explicit language of Pearlman at that passage and in the following one at lines 37-42 of Column 3, which directs that killing lice requires leaving the active on for "usually about 2 to 8 hours, typically overnight" (*ibid*, at lines 37-42).

In contrast, the claimed invention kills lice within one hour, or within an exposure time of only 10 minutes. Pearlman cannot be read to suggest such an outcome for *any* agent—to the contrary, the reference explicitly teaches that killing requires a 2 to 24 times longer exposure time for *all* 'pediculostatic agents' he describes. The reference therefore provides no motivation or guidance to the art whatsoever for use of any active to kill ectoparasites within an hour after, or on 10 minutes of, exposure.

Therefore, to arrive at the invention from Pearlman, one of ordinary skill in the art would have to first ignore the explicit teachings of the reference as to application times. Even if one were willing to do so, the degree of experimentation required to span the gap from Pearlman to the invention is vast.

One would have to providentially choose isopropyl myristate as an active agent out of a vast list of such agents that mentions numerous examples of suitable compounds without mentioning isopropyl myristate at all: "[i]n another embodiment [the first being identification of the agent as virtually any surfactant], the driable pediculostatic agent of the invention is a composition comprising a non-volatile lipid material, a non-volatile fatty alcohol, a non-volatile fatty ester or mixtures thereof." (see, Col. 12, lines 39-51). Of this nearly limitless array of choices, a few fatty esters are suggested, including non-acid compounds, none of which are isopropyl myristate: "cetyl lactate, cetyl octonate, cetyl palminate, glyceryl myristate, glyceryl oleate, glyceryl stearate, glyceryl monoacetate and mixtures thereof." (Col. 13, lines 1-5).

Indeed, providence—coupled with undue experimentation--would be necessary for one to select isopropyl myristate as the correct choice from such a broad genus. As such, the genus teaching by Pearlman cannot be read to disclose the presently claimed use of a

species, especially the reference fails to even mention the species in question (see, e.g., *In re Jones,* 21 USPQ2d 1941 (Fed.Cir. 1992); *In re Baird*, 29 USPQ2d 1550 (Fed.Cir. 1994); *Fujikawa v. Wattanasin*, 39 USPQ2d 1895 (Fed. Cir. 1996)).

Certainly the examples of Pearlman would be of no help in selecting isopropyl myristate as a killing agent effective within an hour following its administration or on 10 minutes exposure to it. The only composition whose use is exemplified in the application is the commercially available lotion Cetaphil®. The reported results make it quite clear that lice treated with Cetaphil® that wasn't dried onto the hair didn't die for 12 hours, and even those treated with dried Cetaphil® were still alive after 4 hours (not dying for 8) (Col. 15, lines 1-18). Cetaphil®, of course, does not contain isopropyl myristate or, indeed, any fatty acid ester (see, ingredients list at Pearlman, Col. 14, lines 50-56).

Cetaphil® does, however, contain more than one 'pediculostatic agent' as defined by Pearlman, both of which are alcohols; i.e., cetyl alcohol and stearyl alcohol (*id.*, and Col. 12, lines 52-66, identifying cetyl and stearyl alcohol as preferred pediculostatic agents). The reference therefore also fails to enable one to use any one such agent for killing lice, much less isopropyl myristate alone (per Claims 1, 12 and 34), or any agent in an alcohol-free composition (per Claim 1).

It is axiomatic that a prior art reference must enable one of ordinary skill to make the invention without undue experimentation. With respect to the present invention, Pearlman fails to do so, and so cannot be said to render it obvious (see, e.g., MPEP 2121.01, citing *In re Hoeksema,* 399 F.2d 269, 158 USPQ 596 (CCPA 1968). *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) and, *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985; see also, *Impax v. Aventis Pharmaceuticals,* 88 USPQ2d 1381 (Fed.Cir., Oct. 3, 2008), citing *Finisar Corp. v. DirecTV Group,* 523 F.3dd 1323, 1336 (Fed.Cir. 2008) and *In re Omeprzole Patent Litig.*, 483 F.3d 1364, 1379 (Fed.Cir. 2007)).

Lastly, even if one were to stumble upon isopropyl myristate as a potential agent against lice, then ignore Pearlman's explicit direction to apply it for longer than the hour claimed to kill lice, the result would still not be the invention of Claim 1. To get that far, one would have to ignore even more of Pearlman, which repeatedly suggests the use of alcohols (e.g., Col. 12, lines 39-65) in the composition. Only ignoring that teaching as well would allow one to arrive at the claimed *alcohol-free* composition of Claim 1.

In summary:

1. The claimed invention requires killing of lice within one hour following administration of the composition or on exposure to it of only 10 minutes duration. Pearlman teaches away from both of those limitations by teaching that lice treated with his compositions are merely immobilized within that time frame, but only killed on exposure times of at least 2 to 24 hours (with a minimum of 4 hours exposure being required for the exemplified composition).

2. The claimed invention requires use of isopropyl myristate as the sole killing agent. Pearlman fails to provide any guidance toward selection of isopropyl myristate as even a pediculocidal (immobilizing) agent, or for use of any such agent in the absence of another.

3. The claimed invention requires use of an alcohol-free composition. Pearlman teaches away from the limitation by teaching that alcohols are suitable, even preferred, 'pediculostatic' agents. The reference does not contain any mention of an alcohol-free composition.

For at least the above reasons, in addition to those earlier made of record, Applicants respectfully submit that Pearlman does not support rejection of the claims under Section 103. Reconsideration and withdrawal of the rejection is therefore requested.

CONCLUSION

All of the pending claims (1-4, 8, 10, 12-16, 19, 21, 32 and 34-41) are believed to be in condition for allowance. Reconsideration of the claims rejections is therefore requested as outlined above.

No fees are believed to be due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,

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